



UNIVERSITEIT VAN DIE VRYSTAAT UNIVERSITY OF THE FREE STATE



Direkteur: Fakulteitsadministrasie
Fakulteit Gesondheidswetenskappe
✉ 339 BLOEMFONTEIN 9300
REPUBLIEK VAN SUID-AFRIKA
☎ (051) 405 3013 / 401 2847
📠 (051) 444 3103
✉ gndkt@med.uovs.ac.za

Research Division
Internal Post Box C40
✉ (051) 4053654

Mrs G Niemand

Director: Faculty Administration
Faculty of Health Sciences
✉ 339 BLOEMFONTEIN 9300
REPUBLIC OF SOUTH AFRICA
☎ (051) 405 3013 / 401 2847
📠 (051) 444 3103
✉ gndkt@med.uovs.ac.za

E-mail address: gndkgcn@med.uovs.ac.za

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DR AM VAN DER BIJL
FARMOVS-PAREXEL
INTERNAL POST BOX C6
UNIVERSITY OF THE FREE STATE

Dear Dr van der Bijl

ETOVS NR 31/03

RESEARCHER: DR AM VAN DER BIJL

PROJECT TITLE: A RANDOMIZED, CONTROLLED, CROSSOVER STUDY ASSESSING THE EXERCISE PERFORMANCE IN ADULT MALE SMOKERS COMPARING ELECTRICALLY HEATED CIGARETTES, CONVENTIONAL CIGARETTES AND SMOKING. (FARMOVS 310/2002)

You are hereby informed that the following were approved by the Ethics Committee during their meeting held on the 18th February 2003:

- Protocol Final Version dated 05 February 2003
- English and Afrikaans Subject Information Sheets and Statements of Informed Consent dated 5 February 2003
- CV's of the following investigators: Drs van der Bijl, A Coetze, F Burger, PJ Jordaan, FPJ le Roux, JH Potgieter, J Rossouw, J Terblanche
- Investigator's Brochure Edition 1.0 dated July 10, 2002
- Insurance Certificates

The Committee recommended that the following addition has to be made in the Informed Consent: "Smoking is harmful to your health".

Your attention is kindly drawn to the following:

- Failure to submit a progress report not later than one year after approval of the project may result in the termination of the study.
- That all extinctions, amendments, serious adverse events, termination of a study etc have to be reported to the Ethics Committee
- It is compulsory in all relevant studies to obtain MCC-approval prior to commencement
- These documents have been accepted as complying with the Ethics Standards for Clinical Research based on FDA, ICH GCP and Declaration of Helsinki guidelines
- Translations of the Subject Information Leaflet and Consent Form have to be submitted prior to commencement of a study.

Will you please quote the Etovs number as indicated above in subsequent correspondence, reports and enquiries.

Yours faithfully,

For DIRECTOR: MEDICINE ADMINISTRATION